APR - 6 2001

K010776

510(k) SUMMARY

Device: Trinity Polyaxial Pedicle Screw and 6mm Titanium Spinal Rod

Date: 03/12/01

Applicant's name: Corin USA
10500 University Center Drive, Suite 190
Tampa, FL 33612

Phone: (813) 977-4469
Fax: (813) 979-0042

Contact person: Joel Batts, Regulatory Affairs Manager

Classification name: Spondylolisthesis spinal fixation device

Product codes: MNH

C.F.R. section: 21.888.3070

Device class: II

Classification panel: Orthopedic

Indications for use

Properly used the Mehdian Lumbo-Sacral System, is intended to provide stabilisation until a solid fusion develops. Intended uses and indications are as follows:

1. When pedicle, posterior fixation is used, the system, consisting of sacral/iliac screws, pedicle screws, spacers, hooks, rod/plates and crossbraces, is intended for use in skeletally mature patients:

a) having a severe spondylolisthesis (grades 3 and 4) at the fifth lumbar-first

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sacral L5-S1 vertebral joint
b) who are receiving fusions using autogenous bone graft only
c) who are having the device fixed or attached to the lumbar and sacral spine (L3- S1)
d) who are having the device removed after the development of a solid fusion mass

Although the levels of fusion may not go above the L5-S1 joint, the levels of pedicle screw fixation may be L3-S1.

The intended use of the Mehdian system, as described in its labeling, has not changed as a result of the addition of the Trinity Polyaxial Screw. The fundamental scientific technology has also not changed in the design of the Trinity Polyaxial Screw, which is based on modifications to the Mehdian monoaxial screw.

Device description
The Trinity Polyaxial Screw (TPS) is a variable-position head pedicle screw with a design based on the monoaxial pedicle screw that is a part of the previously approved Mehdian Lumbo-Sacral System (K973425). TPS is comprised of the following six (6) separate components, listed in order of assembly: screw, body (screw head), boat, collar, locking cap, and grub screw.

TPS is available in 2 styles – one which accepts 5mm rods and one which accepts 6mm rods. A 6mm TPS option was included to provide the surgeon with a stronger construct in the event patient demands (ie, somatotype) required such.

Substantial equivalence basis
The applicant claims substantial equivalence (SE) of the Trinity Polyaxial Screw (TPS) to the previously approved Mehdian monoaxial screw; the 6mm titanium spinal rod to the previously approved 5mm titanium spinal rod. Both the Mehdian monoaxial screw and 5mm titanium spinal rod were cleared in K973425.

There are five (5) modifications that have been made to the Mehdian monoaxial screw, resulting in the TPS:

1. Addition of a moveable (polyaxial) screw head
2. Addition of a "boat" component within screw head/body
3. Reduction in height of collar
4. Change from external locking cap thread/internal screw head thread design to internal locking cap thread/external screw head thread design
5. Change from central hexagon drive hole on locking cap to three (3) single drive holes toward outside of cap; these single drive holes are at 120° of each other.

Mechanical testing was carried out according to ASTM 1717-96 to validate the above design changes that lead to the TPS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2001

Mr. Joel K. Batts
Regulatory Affairs Manager
Corin U.S.A.
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Re: K010776
Trade Name: Trinity Polyaxial Screw, 6mm Rod
Regulatory Class: II
Product Code: MNH
Dated: March 13, 2000
Received: March 14, 2000

Dear Mr. Batts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K010776

DEVICE NAME: TRINITY POLYAXIAL SCREW, 6MM ROD

INDICATIONS FOR USE:

Properly used the Mehdian Lumbo-Sacral System is intended to provide stabilisation until a solid fusion develops. Intended uses and indications are as follows:

1. When pedicle, posterior fixation is used, the system, consisting of sacral/iliac screws, pedicle screws, spacers, hooks, rod/plates and crossbraces, is intended for use in skeletally mature patients:

    a) having a severe spondylolisthesis (grades 3 and 4) at the fifth lumbar-first sacral L5-S1 vertebral joint
    b) who are receiving fusions using autogenous bone graft only
    c) who are having the device fixed or attached to the lumbar and sacral spine (L3-S1)
    d) who are having the device removed after the development of a solid fusion mass

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The intended use of the Mehdian system, as described in its labeling, has not changed as a result of the addition of the Trinity Polyaxial Screw. The fundamental scientific technology has also not changed in the design of the Trinity Polyaxial Screw, which is based on modifications to the Mehdian monoaxial screw.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010776